

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
HUNTINGTON DIVISION

3  
4 GENBIOPRO, INC., : CIVIL ACTION NUMBER  
5 : 3:23-cv-00058  
6 Plaintiff, :  
7 -vs- :  
8 MARK A. SORSAIA, in his official :  
9 capacity as Prosecuting Attorney :  
10 of Putnam County and :  
11 PATRICK MORRISEY, in his :  
12 official capacity as Attorney :  
13 General of West Virginia, :  
14 Defendants. :  
15 X

**MOTION HEARING  
BEFORE THE HONORABLE ROBERT C. CHAMBERS,  
UNITED STATES DISTRICT JUDGE  
MONDAY, APRIL 24, 2023**

22 Proceedings recorded by mechanical stenography,  
transcript produced by computer.

CATHERINE SCHUTTE-STANT, RDR, CRR  
Federal Official Court Reporter  
300 Virginia Street, East  
Charleston, WV 25301

1           **APPEARANCES:**

2           **For the Plaintiff:**

**ANTHONY J. MAJESTRO, ESQUIRE**

Powell & Majestro  
Suite P-1200  
405 Capitol Street  
Charleston, WV 25301

5           **DAVID C. FREDERICK, ESQUIRE**

6           Kellogg Hansen Todd Figel &  
7           Frederick  
8           Suite 400  
9           1615 M Street, NW  
10          Washington, D.C. 20036

11          **For the Defendant**  
12          **Mark A. Sorsaia:**

**JENNIFER SCRAGG KARR, ESQUIRE**  
Putnam County Judicial Building  
12093 Winfield Road  
Winfield, WV 25213

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14

15          **For the Defendant**  
16          **Patrick Morrisey:**

**CURTIS R. CAPEHART, ESQUIRE**  
West Virginia Attorney General's  
Office  
Building 1, Room 26e  
1900 Kanawha Boulevard, East  
Charleston, WV 25305

GenBioPro v Sorsaia, et. Al.

1                     (The following proceedings were held before the  
2 Honorable Robert C. Chambers, United States District Judge,  
3 in the case of *GenBioPro, Inc., versus Mark A. Sorsaia*, in  
4 his capacity as Prosecuting Attorney of Putnam County, et.  
5 al., on April 24, 2023, at Huntington, West Virginia,  
6 beginning at 2:02 p.m.)

7                     COURT SECURITY OFFICER: All rise.

8                     THE COURT: Good afternoon.

9                     Before we start the proceeding, I'm advised that we  
10 have a number of individuals who are participating by  
11 listening by telephone, so I want to instruct them that they  
12 are reminded that there is a general prohibition against any  
13 sort of recording or rebroadcasting of court proceedings. A  
14 violation of that prohibition could result in sanctions. So  
15 please make sure that you abide by that requirement.

16                     I'm also advised they've already been instructed to  
17 mute their devices, so hopefully that will continue  
18 throughout.

19                     So I appreciate counsel quickly making themselves  
20 available for this hearing after the Court contacted you.

21                     I've done an order which explains that I'm limiting  
22 this hearing to a discussion of the standing issues  
23 presented by the plaintiff's complaint.

24                     Obviously, it's a necessary part of the Court's  
25 deliberation over the pending motions to determine that

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1 there is adequate standing as to both of the defendants, and  
2 it's a threshold requirement. So I felt it appropriate to  
3 have a separate -- and hopefully successfully quickly  
4 resolving this one way or the other in doing this as a first  
5 step. And consequently, I asked plaintiffs to be prepared  
6 to first outline, since plaintiff has the burden of  
7 establishing standing, the basis in the Complaint for  
8 standing, and then to respond to the arguments that you've  
9 seen raised by the defendant.

10 So who is presenting on behalf of the plaintiff?

11 MR. MAJESTRO: Your Honor, Anthony Majestro for  
12 the plaintiff. I would like to introduce David Fredrick  
13 from Kellogg Hansen in Washington, D.C., who will be  
14 handling the argument for the plaintiffs.

15 THE COURT: All right. Thank you.

16 Welcome, Mr. Frederick.

17 MR. FREDERICK: Your Honor, is it all right that I  
18 speak from here?

19 THE COURT: It is. I'm going to ask all of you to  
20 use the microphones whenever possible. The acoustics in  
21 this courtroom aren't particularly good, and the court  
22 reporter is using a recording and -- using headphones to  
23 hear through the system, and so it is necessary for you to  
24 use the microphones.

25 With that, go ahead.

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1                   MR. FREDERICK: Thank you, Your Honor.

2                   David Frederick for plaintiff, GenBioPro.

3                   We brought this case to challenge West Virginia's  
4                   Criminal Abortion Ban and associated restrictions under two  
5                   theories. The Ban is preempted by the Food and Drug  
6                   Administration Amendments Act of 2007, the FDAAA, and the  
7                   associated FDA rules and statutes, and it breaches the  
8                   Commerce Clause of the U.S. Constitution.

9                   The Ban seeks to override the FDA's approval of  
10                  mifepristone for its indicated use in the early termination  
11                  of pregnancy.

12                  You've directed us to address standing. And that's  
13                  what I'd like to focus on in my presentation today.

14                  The tests for standing is three-fold: injury in fact,  
15                  sufficient causal connection for the injury; and the conduct  
16                  complained of; and the likelihood that the injury will be  
17                  redressed by a favorable decision.

18                  Now, I want to address the pleading standard for  
19                  standing because we are here on a motion to dismiss. And  
20                  the Supreme Court said in the *Susan B. Anthony* case the test  
21                  for standing and the pleading requirements for standing  
22                  depend on the level at which the challenge is being made.

23                  Because we are at the motion to dismiss stage, the  
24                  normal pleadings' standard for a motion to dismiss apply,  
25                  which means that we are charged with pleading plausibly that

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1 we have standing.

2 Now, we understand and appreciate, Your Honor, that at  
3 summary judgment we will be called upon to present proof  
4 that would support the allegations made in the Complaint.  
5 And we are prepared to do so. And if asked by the Court, I  
6 can outline some of those proofs that we would expect to be  
7 presenting.

8 But for purposes of this argument, we believe we have  
9 plausibly pleaded standing, because we plausibly pleaded  
10 that we are injured by the state's ban, that it is causally  
11 connected to the statements made by the attorney general and  
12 the Putnam prosecutor, and that a favorable decision by you  
13 declaring the state's ban and associated restrictions to be  
14 unconstitutional under the Supremacy Clause and the dormant  
15 Commerce Clause would redress the harm that we suffer.

16 So with that, let me just start by saying that the  
17 generic form of mifepristone is GenBioPro's principal  
18 product, and it sells throughout the United States, as we  
19 pleaded in the Complaint. We seek to sell in West  
20 Virginia -- or seek to have distributed for sale because  
21 GenBioPro is not a direct seller -- but through pharmacies,  
22 telemedicine providers, mail health, pharmacies, et cetera,  
23 and other distributors; and is precluded by doing so by the  
24 statute enacted by the West Virginia legislature.

25 So the very first point is economic harm.

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1           The Fourth Circuit has called this, quote, the  
2 paradigmatic form of an injury to confer standing. That's  
3 the *Maryland Shall Issue* case decided by the Fourth Circuit  
4 in 2020, and it quotes a decision out of this court, *Air*  
5 *Evac EMS*. That was a case involving interplay with health  
6 providers.

7           Now, the attorney general admits that the Ban causes  
8 harm to GenBioPro's, quote, bottom line. And that ought to  
9 be enough at the pleading stage for us plausibly to show  
10 economic injury, that one concession there.

11           As the Fourth Circuit held in *Maryland Shall Issue*,  
12 even a small amount of loss of money is ordinarily an  
13 injury. And like a gun owner in *Maryland Shall Issue* and  
14 the beer vendor in the Supreme Court case of *Craig versus*  
15 *Boren*, GenBioPro has lost business opportunities as a result  
16 of West Virginia's unconstitutional laws.

17           THE COURT: Here's the rub -- and this is what I  
18 think the defendant points to -- GenBioPro does not allege  
19 in the Complaint that they've had any past sales.

20           As I understand it, you've been in the business since  
21 about 2019?

22           MR. FREDERICK: That's correct.

23           THE COURT: And so -- and you say that it's a  
24 nationwide business. Fair enough. But you didn't allege  
25 that you were already selling or already even taking steps

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1 to certify doctors or pharmacies under the more recent REMS.

2 So when I looked at these cases, frankly, the first  
3 thing that occurred to me is that these other plaintiffs who  
4 you -- in the cases you noted were established as already  
5 doing business and already had direct sales to their  
6 customers in the states where they brought the cases and  
7 were asserting standing.

8 And defendant argues that you've only stated a  
9 generalized intention to do business in West Virginia  
10 and/or other states, but you haven't actually done business  
11 in West Virginia.

12 So do these cases not require something more than just  
13 an intention to engage in the business at some point?

14 MR. FREDERICK: They do not. There is not a  
15 single case on point that they have cited that requires past  
16 sales.

17 THE COURT: Are there any cases that you've come  
18 across where a similarly situated plaintiff sought standing  
19 based on economic harm where they didn't already have past  
20 sales or an existing customer relationship within the  
21 targeted state?

22 MR. FREDERICK: Yes. The Fourth Circuit cited a  
23 case out of the Seventh Circuit called *Ezell*. And if I --  
24 it's called *Ezell versus the City of Chicago*. That was a  
25 case involving firing range practice areas.

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1           The company was one that said in the reported decision,  
2 we sell throughout the United States, and we have intent to  
3 create a firing range in the City of Chicago. Because of  
4 the ordinance passed by the City of Chicago, the firing  
5 range facility operator was not able to provide a firing  
6 range facility. It obviously had not done any business in  
7 the City of Chicago. It wanted to do business. And but for  
8 the existence of the ordinance banning the firing range  
9 facility, it would have been permitted to do so.

10           The Seventh Circuit said there is standing to bring the  
11 challenge under the Constitution. That was a Second  
12 Amendment case.

13           But the Seventh Circuit said that there was standing  
14 because there was economic harm due to the loss of  
15 prospective sales. That case was cited with approval in  
16 *Maryland Shall Issue*. *Maryland Shall Issue* was a case  
17 involving those sales at the time to young people who didn't  
18 have the license that was required by the state. So these  
19 were all prospective sales that were being complained of.

20           THE COURT: But they were already in the state,  
21 doing business and making sales?

22           MR. FREDERICK: Yes, Your Honor. And if -- I  
23 would say it's not a pleading requirement. Because the  
24 pleading requirement is that there be a loss potential for  
25 sales.

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1           We can establish evidence, if put to the proof, that  
2 there have been past sales by GenBioPro of mifepristone in  
3 West Virginia. We didn't think it was necessary to plead  
4 that.

5           We would urge you to not require us to go through the  
6 mechanics of amending the Complaint. We can provide  
7 evidence of that, if necessary, at cross-motions for summary  
8 judgment.

9           THE COURT: I wish you had said that when you saw  
10 their initial attack -- and I don't -- by saying I wish you  
11 had, I'm not criticizing you, I just think if you -- I think  
12 it's really clear if you would have alleged that you were  
13 already conducting transactions -- and I'm not saying you're  
14 wrong. I'm still pondering all this. And I understand your  
15 position and why you would take the position that you don't  
16 need to allege nor even have had past sales.

17           MR. FREDERICK: There is also a Tenth Circuit case  
18 called *303 Creative*. And in that case, the website designer  
19 had not yet started to make websites that would be -- that  
20 would implicate questions about same-sex marriage. There  
21 was only a prospective creation of the website there.

22           And let me explain to you exactly why it shouldn't  
23 matter in this particular case.

24           West Virginia enacted its Criminal Abortion Ban in  
25 September of 2022. To our knowledge, people complied with

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1 that and have not had any sales in that time period.

2 In January of 2023, the FDA promulgated new risk  
3 mitigation strategies. These are REMS.

4 THE COURT: Right.

5 MR. FREDERICK: That is the name for them. And  
6 these REMS provided for telemedicine, for mail order  
7 provision of mifepristone. And so the direct collision  
8 occurred. And so if you would suppose that there had been  
9 an abortion ban throughout this entire period, it would be  
10 odd to think that the plaintiff can only get standing by  
11 showing violation of the law through sales that would be in  
12 conflict with the state law.

13 GenBioPro is a law-abiding company and is seeking  
14 through legal means to come up with the appropriate answer.

15 And so if you think about the logic of their position,  
16 it actually doesn't make sense, because it would mean that a  
17 state could act unconstitutionally to constrict an  
18 out-of-state distributor's products. And then if the  
19 federal government changed the rules that would have enabled  
20 that product to be distributed for sale in a state, under  
21 their theory of standing, there is no standing because there  
22 was no prior sale.

23 And so I think that if you think about it from a  
24 logical perspective, it can't be a pleading standard.

25 If you look at *Craig versus Boren*, Maryland Shall

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1       Issue, the Ezell case, there was no -- there was no prior  
2 sale to the target audience. It can't be a pleading  
3 requirement.

4           But if you think that we need to provide evidence to  
5 that effect, we can show some evidence of past sales in  
6 prior periods.

7           So if that's the only issue that's hanging you up about  
8 standing, I hope I've adequately --

9           THE COURT: Well, I appreciate -- and you have  
10 responded to my questions, but I'm not going to say that's  
11 the only issue hanging me up.

12           I reserve the right to review all of this and make a  
13 ruling based upon all of it. But you've certainly explained  
14 your injury in fact theory. And I understand when I looked  
15 at these cases, one of the things that occurred to me,  
16 especially in the context of the defendants' argument, was  
17 that even though you had been in the business in 2019 -- and  
18 I understand that the recent REMS changed the landscape  
19 considerably, and would have expanded the possibility of  
20 business -- as you've acknowledged, it's a pleading stage  
21 standard. But the Court can't just accept a conclusory  
22 statement that we have standing because we have an injury in  
23 fact. You have to demonstrate, plausibly allege what that  
24 is. And I appreciate your answering those questions for me  
25 here today.

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1                   MR. FREDERICK: All right. And I can point you to  
2 the paragraphs of the Complaint that we think adequately --

3                   THE COURT: Why don't we do that, just to make  
4 sure we are on the same page as we go through this.

5                   MR. FREDERICK: Sure. So paragraph 3 pleads that  
6 the company provides medication abortion, and that is a form  
7 of ending pregnancy that is used now in more than half of  
8 all instances in the United States.

9                   Paragraph 11 explains that the Ban constricts the  
10 market for mifepristone.

11                  Paragraph 74 explains that the West Virginia sales Ban  
12 constricts West Virginia sales.

13                  Paragraphs 78 through 80 explain how pharmacies, both  
14 brick and mortar pharmacies like Walgreens and CVS, and a  
15 mail order pharmacy known as HoneyBee, would provide  
16 mifepristone to persons here in the state.

17                  And paragraph 110 alleges that there's a constriction  
18 of the market.

19                  We think those -- we easily satisfy plausibility.

20                  THE COURT: Right. And, as I recall, you  
21 explicitly alleged in one of those paragraphs that the big  
22 pharmacies had publicly stated an intention at some point to  
23 distribute the drugs.

24                  Is that correct?

25                  MR. FREDERICK: That's correct.

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1                   THE COURT: And I guess that since -- maybe not so  
2 clear, as I understand it, and -- but it's not part of the  
3 pleadings -- one or more of these pharmacies have now  
4 indicated some hesitation about getting into the  
5 distribution of mifepristone in those states where attorney  
6 generals have said that there should -- that the Ban should  
7 prohibit it.

8                   MR. FREDERICK: That brings me to third-party  
9 enforcement, because the attorney general here has signed  
10 one of those letters that threaten Walgreens, one of the  
11 pharmacies that said it would comply with the 2023 REMS to  
12 provide mifepristone in its pharmacy.

13                  And in the February 1 letter that the attorney general  
14 cosigned with the Attorney General of Kansas, threatened  
15 Walgreens with a civil RICO action.

16                  And that threat, we think, brings four square in the  
17 third-party enforcement doctrine of standing.

18                  THE COURT: Before we get to that, let's cover the  
19 other bases.

20                  You've acknowledged injury in fact, traceability, and  
21 redressability. So let's not get into the local prosecutor  
22 and the pre-enforcement issue raised there.

23                  Tell me what your response is to the defendants'  
24 arguments about traceability and redressability with respect  
25 to your injury in fact based standing as a -- for economic

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1 loss.

2 MR. FREDERICK: Sure. Let me start with  
3 traceability.

4 Both of the defendants have the authority to enforce  
5 the law in West Virginia, and neither have disavowed an  
6 enforcement intent relating to the Ban.

7 Under the *Susan B. Anthony* case, that is sufficient for  
8 justiciability in terms of traceability where the government  
9 has not disavowed enforcement of the unconstitutional law.

10 We cite other cases in our opposition briefs at 7 and  
11 4, that I think well explained the principal here.

12 The defendants' commitment to enforcing an  
13 unconstitutional law is causing West Virginians not to  
14 purchase or prescribe GenBioPro's product. And that's  
15 sufficient for traceability.

16 The *303 Creative* case is on point for this, where the  
17 Court said an injury in fact is fairly traceable to a  
18 defendant if the defendant is charged with the  
19 responsibility to enforce the statute.

20 And in the Fourth Circuit, the *Libertarian Party* case  
21 says that traceability only requires the defendants have,  
22 quote, "some part" in causing plaintiff's harm.

23 Now, as the sequence that you described, which will  
24 play itself out in pleading and, in fact, the statements of  
25 enforcement by the defendants have chilled the market for

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1 GenBioPro's product. That's sufficient to show the  
2 traceability necessary for standing purposes to challenge  
3 the unconstitutionality.

4 THE COURT: I take it that the enforcement you're  
5 talking about, primarily, is enforcement of the so-called  
6 Unborn Child Act, the Ban -- abortion prohibition, the most  
7 recent of the acts by the state legislature. And as I read  
8 it, it certainly greatly restricts when any abortion can be  
9 performed within the state. It requires, of course, that it  
10 be by a medical provider. And that in combination with the  
11 earlier statute, which literally criminalizes an illegal  
12 abortion, you're really talking about enforcement, both in  
13 terms of exposure to a criminal charge, as well as exposure  
14 to a licensing revocation or suspension with regard to any  
15 doctor or pharmacy.

16 MR. FREDERICK: That's correct. And even  
17 GenBioPro itself, even though it is an out-of-state  
18 distributor of mifepristone, falls within an overly broad  
19 and vague definition of an attempt to perform or induce an  
20 abortion. The definition under state code 16-2R-2 says that  
21 abortion means -- that an attempt to perform or induce means  
22 an act that constitutes a substantial step in the course of  
23 conduct intended to culminate in an abortion.

24 THE COURT: Almost a state Comstock Act.  
25

MR. FREDERICK: Well, it was -- you know, we can

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1 talk about the Comstock Act in due course, but I just want  
2 to start with the definition, which actually leads directly  
3 one to think that it could conceivably encompass through its  
4 vagueness a company like GenBioPro.

5 So I think that for these reasons, the traceability  
6 goes right back to the statute and goes right back to the  
7 activities that GenBioPro is seeking through its  
8 distribution of mifepristone in West Virginia.

9 Now, as to redressability, we've asked for declaratory  
10 judgment that the law is unconstitutional. The pharmacies  
11 that we cited in our Complaint said that in those states  
12 where it is not illegal, they would distribute the product  
13 in their pharmacies. We think that's sufficient for  
14 redressability.

15 The laws that have been enforced by the defendants have  
16 caused the injury from preventing the sale of the product in  
17 the state. So we think we meet each of the elements of  
18 standing just as a direct entity by GenBioPro itself.

19 We think it also satisfies third-party standing,  
20 because the providers that you mentioned who face the harm  
21 and risk of possible enforcement against them are within the  
22 zone protectable by a vendor.

23 *Craig versus Boren* established that principle almost 50  
24 years ago when the gentleman who wanted to buy 3.2 beer  
25 underage eventually got older than the age prescribed by the

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1       statute, but the Supreme Court said that the seller of the  
2       3.2 beer was able to assert third-party standing on behalf  
3       of those whose equal protection rights were being bridged by  
4       the Oklahoma statute there.

5           So we think that there is adequate grounds for both the  
6       third-party standing, the threat of enforcement provides  
7       adequate standing, and the ability of the vendor here in a  
8       better position actually because of hindrances, the cost of  
9       litigation, the expense, the difficulty of litigation for  
10      individuals, to say nothing of, you know, the concerns with  
11      making our product available for sale in the state, I think  
12      adequately satisfies all of the relevant standing  
13      requirements.

14           THE COURT: And then with respect to threat of  
15       enforcement as a basis to hold in the county prosecutor, it  
16       is because the county prosecutor could seek criminal  
17       enforcement against your customers, but you argue, even  
18       against GenBioPro?

19           MR. FREDERICK: Well, that -- I'm not inviting  
20       that, Your Honor.

21           THE COURT: Right.

22           MR. FREDERICK: I'm saying that the vagueness of  
23       the statute raises the specter of that, and that is  
24       sufficient for standing.

25           The fact that there are Walgreens stores and pharmacies

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1       in the Putnam County area that are potentially subject to  
2 prosecution is sufficient for the threat of enforcement  
3 aspect of standing. And -- and it is a real thing, based on  
4 the circumstances that I've laid out, that we can make it a  
5 full or factual presentation at summary judgment if the  
6 Court views the pleading plausible now is sufficient, which  
7 we think that the Court should.

8                     THE COURT: All right. Thank you.

9                     MR. FREDERICK: I've got nothing further on  
10 standing, unless there are questions that you have. I'd  
11 like to save some time for rebuttal, if I might.

12                     THE COURT: Oh, you will. That's fine.

13                     All right.

14                     MR. CAPEHART: Thank you, Your Honor.

15                     I just want to make sure everyone can hear. Is the  
16 microphone picking up well?

17                     (Pause.)

18                     THE COURT: I'm sorry. Go ahead.

19                     MR. CAPEHART: Not a problem, Your Honor.

20                     First of all, I just want to take a moment to clarify a  
21 couple of things, and especially about how the Unborn Child  
22 Protection Act works, especially following some of the  
23 concerns about the definition of abortion, because I'm not  
24 sure -- I'm not reading it maybe the way that counsel is  
25 over here.

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1           Looking at it, an abortion means the use of any  
2 instrument, medicine, drug, or any other substance or device  
3 with the intent to terminate a pregnancy of a patient known  
4 to be pregnant, and with an intent to cause the death and  
5 expulsion or removal of an embryo or fetus.

6           It also goes on to clarify what the definition does not  
7 mean. I'm not sure I've seen anything from there that leads  
8 me to believe that anyone would ever try to look at the  
9 manufacturer of an abortion drug and the shipment or sale of  
10 that abortion drug in West Virginia as somehow something to  
11 be controlled or to be looked at as an abortion.

12           THE COURT: It wouldn't be the use of the  
13 medicine?

14           MR. CAPEHART: The use of the medicine would be,  
15 but the manufacturer, absolutely not.

16           THE COURT: Well, okay. I mean, here, you're  
17 talking about the manufacture and distribution through the  
18 sale.

19           MR. CAPEHART: Correct.

20           THE COURT: I take it that at this point neither  
21 the attorney general nor the prosecutor have announced any  
22 policy response to that argument and disavowed any  
23 possibility of bringing a criminal prosecution against the  
24 maker of the drug. And I say that in the context, frankly,  
25 of you raising the Comstock Act as a possible violation.

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1 It's federal law. It's not enforceable by you guys, but  
2 you've raised that as a possible consequence of the  
3 manufacturer's decision to produce or to manufacture and  
4 sell in the state, and thereby transport over interstate  
5 commerce.

6 So it really -- I appreciate what you're saying, but  
7 I -- I don't think I could find that as a persuasive  
8 declaration that there is no exposure to criminal  
9 prosecution.

10 MR. CAPEHART: Well, and I appreciate the  
11 opportunity here on the record to clarify some of these  
12 things, because I think there has been a bit of a  
13 misapprehension as to exactly what the purpose of the  
14 statute is. And I can't speak to what a prosecuting  
15 attorney would do as the principal prosecuting arm of the  
16 state government vis-a-vis the criminal code, 61-2-8.  
17 That's the prosecutor's decision. I'll let the prosecutor's  
18 office speak to that.

19 But in terms of our read of what the Unborn Child  
20 Protection Act was about, it's all about the regulation of  
21 the practice of abortion, and also of the practice of  
22 medicine as it relates thereto. It's limiting only that  
23 practice to those persons identified within the statute as  
24 being capable of performing legal abortions that may  
25 continue and may happen within the bounds of the Unborn

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1 Child Protection Act, which there certainly are some.

2 THE COURT: Even if that is the case, does that  
3 really change the Court's analysis? The plaintiffs have  
4 asserted that they have third-party standing on behalf of  
5 their putative customers, and those are the people that are  
6 clearly exposed to criminal prosecution if they use the  
7 plaintiff's product to perform an abortion.

8 MR. CAPEHART: Not to step on the prosecutor's  
9 toes, but my reading of the criminal statute of 61-2-8 is to  
10 clarify that those persons who are not identified within the  
11 Unborn Child Protection Act as being permitted to perform  
12 abortions are creating -- excuse me -- are performing a  
13 criminal act to induce or perform an abortion.

14 That clarifies that only those persons identified in  
15 the Unborn Child Protection Act may ever be the group of  
16 persons who could conduct a legal abortion. Anyone else,  
17 potentially, is subject to criminal prosecution.

18 THE COURT: Well, maybe I'm missing something  
19 here.

20 So the state's criminal statute criminalizes abortions  
21 performed other than those that are narrowly permitted under  
22 the statute.

23 MR. CAPEHART: Correct.

24 THE COURT: So the plaintiffs are arguing that  
25 that narrow permission for abortion under the West Virginia

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1       statute, and particularly the most recent one, effectively  
2       limits when their product can be used by a medical provider  
3       in West Virginia to perform an abortion. And so I -- it's  
4       clear to me then that the doctors and/or pharmacies who  
5       use -- who purchase and use mifepristone in a way that's  
6       outside of the West Virginia statute are clearly subject to  
7       criminal prosecution.

8           What am I missing?

9           MR. CAPEHART: You're saying that if someone were  
10          to perform a purely elective abortion, which the Unborn  
11          Child Protection Act does not permit, that would be an act  
12          outside of the law, that those are no longer legal in West  
13          Virginia.

14           THE COURT: Right.

15           MR. CAPEHART: And anyone who wants to perform one  
16          of those violates the Unborn Child Protection Act, and then  
17          similarly would be subject to some kind of criminal  
18          prosecution. But that's about the practice of abortion.

19           That's not about this manufacturer or their product or  
20          how someone utilizes their product. Their product is  
21          utilized perfectly legally. And as I read it, I don't see  
22          how use of their product subjects them to liability any more  
23          than the use of the Louisville Slugger crime subjects --

24           THE COURT: Well, I believe the whole point of  
25          their lawsuit is that under the Commerce Clause and the

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1       Supremacy Clause the statute you're defending constricts  
2       when their products can be used. And so I don't think  
3       we're -- maybe we are just not connecting with each other.

4           But it seems pretty clear to me that their claims are  
5       that because of the restrictive market for their product  
6       created by West Virginia's strict abortion laws violates --  
7       results in a violation of the Commerce Clause and the  
8       Supremacy Clause.

9           We're going to argue later, obviously, about whether it  
10      does and all that, but those are the two claims that they've  
11      raised, and very clearly they're arguing -- they're claiming  
12      that you have constricted the market for their product and  
13      that's caused them economic injury, and so they have  
14      standing to bring the claims because of their own economic  
15      injury. And, obviously, bringing -- a vendor can bring  
16      claims under the Commerce or Supremacy Clause where they  
17      most likely are here.

18           And so, I mean, maybe I'm missing something that you're  
19      saying and I'm just not able to hear it right.

20           But pretty clearly, it seems to me, they have claimed  
21      injury in fact to bring these claims based upon those  
22      circumstances. And the threat of prosecution arises because  
23      the attorney general and/or the county prosecutor can  
24      prosecute their customers for criminal violations for the  
25      use of their product in performing an abortion that's

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1 outside of the restrictions that the state has imposed.

2 MR. CAPEHART: I guess we just never looked at  
3 that, subjecting them to any kind of criminality.

4 THE COURT: Well, there's two things to think  
5 about here. One is that -- whether they have standing or  
6 not is not dependent upon the cause of action they raise.

7 Clearly, the Court says that standing is determined  
8 based -- it is a constitutional requirement that has to be  
9 met in order to consider a party -- a party who can properly  
10 raise whatever claims they might have. And so they don't  
11 have to have standing just based upon -- they don't have to  
12 prove their economic injury results from a Commerce Clause  
13 or a Supremacy Clause violation.

14 Standing is determined, whether they have a sufficient  
15 interest to be recognized by a court as a proper party to  
16 bring whatever claims they have.

17 And so here, that's obviously what they are claiming,  
18 that they have an economic loss.

19 And I don't think you all dispute the economic loss, or  
20 do you? I mean, is that what you're saying now?

21 MR. CAPEHART: No. I think to the extent that --  
22 that one would state that there may be fewer abortions after  
23 the passing of the statute as compared to before, it's  
24 entirely possible. I don't know that. I haven't seen any  
25 data on that.

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1                   THE COURT: Well, irrespective of -- irrespective  
2 of how many abortions are performed, whether it's up or  
3 down, their claim is that their product will not be able to  
4 be used to the, I guess, sort of the full extent that it's  
5 designed to be used, because of the restrictions the state  
6 imposes.

7                   So that's their injury in fact is the economic loss  
8 from not being able to market and sell their product as  
9 extensively as they otherwise could, given the FDA approval.

10                  MR. CAPEHART: Well, and I guess on that point,  
11 Your Honor, we still believe that that's a bit of a  
12 speculative argument in the first place. And it's -- I  
13 appreciate some of the clarifications that counsel provided.

14                  I don't know that we ever read any of those paragraphs  
15 of the Complaint to assert that there was affirmatively any  
16 sale in West Virginia.

17                  THE COURT: Well, I agree. It's kind of where we  
18 started. They did not allege that they have had any past  
19 sales.

20                  Now, they say that they have, and they could, but we  
21 are not to that point.

22                  Based purely upon their pleading, they did not claim  
23 that they had already had sales. I don't think they even  
24 claimed -- in West Virginia -- I don't think they even  
25 claimed that they had any sort of a contractual or similar

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1 relationship with any doctor or pharmacy.

2 But what they have clearly alleged is that they have  
3 been in the business of making this generic for three years,  
4 and they have sold it widely across the United States. And  
5 they have even claimed that specifically under the latest  
6 REMS -- R-E-M-S -- they could have, and they could  
7 distribute through a pharmacy, and that they specifically  
8 alleged one or more of these big chains announced that they  
9 were going to distribute the drug.

10 And so I agree they haven't alleged what I examined Mr.  
11 Frederick about, past sales, or even a current existing  
12 operation of sales within the state, but they've alleged  
13 something different.

14 And so the question is is that enough?

15 MR. CAPEHART: And we have, obviously, taken the  
16 position, Your Honor, that, no, it's not.

17 The fact that a market participant can come to a market  
18 that it's never been a part of and allege that its share of  
19 the market or its customer base in a market that it's never  
20 been present in has been somehow constricted, even though  
21 they've never had a share of that market, seems like a  
22 bridge too far. Especially, you know, as we've been saying,  
23 I see no reason to believe that there actually have been  
24 sales.

25 In fact, it would be a bit of a concern, perhaps,

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1 because the manufacturer BioPro lacks the manufacturer's  
2 license required by the Board of Pharmacy to send their  
3 materials into West Virginia. That's wholly lacking. So  
4 that would be a violation of West Virginia law.

5 I don't know that that's --

6 THE COURT: I don't mind telling you, when I went  
7 through all this and at that point decided that I wanted to  
8 have a hearing on it to get full argument out here, one of  
9 my concerns about the injury in fact allegations of the  
10 plaintiff is whether or not it fell somehow on that side of  
11 the continuum towards like *Lujan* and those cases, where the  
12 Court talked about people -- plaintiffs can't just sort of  
13 speculate that they are going to do something that would  
14 give them standing.

15 And the Court has been, I guess, fairly clear and  
16 consistent that generalized grievances argue that you can't  
17 just come in and say, well, I'm one of the many people who  
18 object to this. I don't like this policy.

19 That's not enough to give standing. Taxpayers don't  
20 automatically have standing to challenge every spending  
21 decision.

22 And so here, my dilemma was looking at, you know, sort  
23 of the continuum of conduct that might fall within the  
24 economic loss line. Have they crossed that threshold from  
25 being sort of speculative and generalized intent to do

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1 something, like conduct sales, or -- or do they meet the  
2 test because of what they've done.

3 And, you know, I'm not going to -- I'm not going to  
4 decide this sitting up here on the bench today. I never  
5 feel comfortable doing that. But, to be honest with you,  
6 because I want you to be able to respond, the closer we've  
7 gotten to this hearing, the more inclined I am to conclude  
8 that there is injury in fact; that they don't have to have  
9 that level of contact and sales within the state that they  
10 might have to have for some other purpose; for instance, to  
11 be conducting business for personal jurisdiction or  
12 something like that.

13 Here, this company has been making this generic for  
14 three years. They've alleged that they sell it nationwide.

15 Clearly, under the REMS, they've got a new sort of  
16 class of customers in that pharmacies can deal with this  
17 directly. And they've also got, under the FDA approvals, an  
18 increased sort of possibility of business because doctors  
19 could do it through telemedicine and other things like that.

20 And so, you know, those don't seem -- it doesn't seem  
21 that GenBioPro is just some pharmaceutical company that  
22 wants to get into the business and is coming to West  
23 Virginia to challenge restrictive laws.

24 They are in the business. And it sounds like they've  
25 been performing business activities consistent with their

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1 claims. And the claims are not simply conclusory; they're  
2 plausible claims that pharmacies located throughout West  
3 Virginia, including Putnam County, have indicated an  
4 intention -- or at least they had at the time of the suit --  
5 to be involved in the distribution, and that this is a drug  
6 that is becoming more widely-accepted, and is now, as I  
7 think they allege -- and I think I probably read this  
8 somewhere in the papers, too -- it is the predominant form  
9 of medical abortions. That using a -- this drug is more  
10 common than not when it comes to performing a lawful  
11 abortion.

12 So all of that seems to me to start tipping in the  
13 balance much more towards the plaintiff and a finding that  
14 this is not a generalized grievance, this is not a  
15 speculative economic loss, that this is something pretty  
16 direct.

17 MR. CAPEHART: I think our position has always  
18 been that it looks speculative and somewhat remote. And  
19 given the fact, as you said, they received generic approval  
20 in 2019 from FDA, yet have never -- as far as we know from  
21 the pleadings or from some other records -- had any access  
22 to West Virginia or availed themselves of it.

23 So they've been doing it for four years and never been  
24 here before. Now they're here, still with zero contacts,  
25 from everything that we can see. That looks very, very

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1 speculative. And if that there is some sort of intent  
2 desire, hardened goal to be into the West Virginia market,  
3 when that's never been present before or evident in many  
4 ways, again, by the fact that they do not have the single  
5 manufacturer's license that every manufacturer is required  
6 to have when sending their drug products to West Virginia,  
7 that's a pretty easy get. And lacking even that after four  
8 months of litigation doesn't speak to me as though someone  
9 who is really trying to get into the market.

10 THE COURT: All right. I appreciate that.

11 Thank you.

12 What else do you want to say?

13 Well, let me ask you this -- I didn't want to interrupt  
14 you.

15 Mr. Frederick cited a couple cases, a Seventh Circuit  
16 case, and then another one, where there were not direct  
17 sales in the targeted state at or before the time of the  
18 lawsuit being filed. So --

19 MR. CAPEHART: I'm afraid I don't have absolute  
20 command of those right in front of my mind, Your Honor.  
21 But, if I recall correctly, it's still involved with an  
22 outright total ban of the some type of activity I think was  
23 the --

24 THE COURT: The gun range case?

25 MR. CAPEHART: The firing range case, yes. Which

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1       is obviously not the case here. There is nothing in West  
2       Virginia law that serves as any impediment to a drug  
3       manufacturer coming in, marketing and selling it, except the  
4       licensure through the boards of pharmacy and whatnot.

5           THE COURT: In the *Maryland Shall Issue* case and  
6       in the *Craig v Boren*, these were businesses that had a whole  
7       lot more sales going on than just the sales that were  
8       affected by the state's restrictions that were being  
9       challenged.

10          MR. CAPEHART: And they were active in the  
11       marketplace prior to the change in code, which is obviously  
12       not the case here.

13          THE COURT: Okay. Anything else you want to bring  
14       up on traceability or redressability with respect to  
15       GenBioPro standing?

16          MR. CAPEHART: No. I think we've touched on a lot  
17       of the things that I was going to try and get into, Your  
18       Honor.

19          THE COURT: Do you want to address separately  
20       third-party standing?

21          MR. CAPEHART: In terms of redressability? In  
22       terms of --

23          THE COURT: Well, with any of these things, I  
24       guess. I mean, as I understand the law, if a party has  
25       standing, they may also seek third-party standing where they

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1 stand in the shoes of some other personal entity and be able  
2 to bring -- they would have standing to bring claims  
3 consistent with what those claims would be here.

4 And GenBioPro is arguing that it has third-party  
5 standing on behalf of pharmacies and doctors that would  
6 otherwise -- it would be their customers if these  
7 restrictions were found to be -- determined to be  
8 unconstitutional.

9 MR. CAPEHART: Well, and I think in regard to  
10 pharmacies, again, as I was saying earlier, I don't see how  
11 pharmacies are implicated by the statutes that are being  
12 challenged. It's about the practice of medicine, and also  
13 about the criminality of the act of performing an illegal  
14 abortion under state law.

15 The pharmacies don't deal with that. They are simply  
16 in the process -- they exist to dispense medications per  
17 prescriptions by doctors, which is something that a  
18 pharmacy -- and, obviously, talking about mifepristone --  
19 one would have to be properly trained and have the proper  
20 certification under the REMS so that they could dispense it  
21 in the first place.

22 And I may be wrong, but I'm not sure that there is  
23 actually one in West Virginia. I think HoneyBee is a  
24 mail-order pharmacy that is outside West Virginia that wants  
25 to ship them here. But I don't believe there is a physical

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1                   pharmacy in West Virginia that has been certified by  
2                   GenBioPro to dispense their medications.

3                   Again, we don't see how pharmacies are directly  
4                   implicated or regulated by any of the statutes in play. The  
5                   physicians are, but the physicians are through the practice  
6                   of medicine. That's wholly bound to the state to decide.  
7                   That's made that pretty clear.

8                   THE COURT: All right. Okay. Anything else?

9                   MR. CAPEHART: Not at this time.

10                  THE COURT: All right.

11                  MS. SCRAGG KARR: Thank you, Your Honor.

12                  Jennifer Scragg Karr, representing Mark Sorsaia, the  
13                  prosecuting attorney.

14                  THE COURT: Tell me his name again. I have met  
15                  him and I've heard his name for years, but -- well, I've  
16                  read it for years. I don't hear it very often.

17                  MS. SCRAGG KARR: It is Sorsaia.

18                  THE COURT: Sorsaia, all right. All right, thank  
19                  you.

20                  MS. SCRAGG KARR: And so I will just discuss why  
21                  you should dismiss this claim against Mark Sorsaia. And  
22                  that is because, as the prosecuting attorney, he is only in  
23                  the business of prosecuting crimes. And this plaintiff  
24                  doesn't have a stake in the controversy of prosecuting  
25                  crimes, because when you look at what is a crime under our

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1 new state law, the legislature enacted the Chapter 16,  
2 Section 2R. And when you look at that, the only thing that  
3 is an actual crime, when it comes to abortion, is under  
4 61-2-8.

5 And when you read the criminal statute, it actually  
6 exempts a licensed medical professional, and it exempts a  
7 pregnant female who is having --

8 So as it relates to this plaintiff, the plaintiff would  
9 be dispensing a pill pursuant to a licensed medical  
10 professional requesting it, giving a prescription, and the  
11 pharmacist filling it. So because the doctor and the  
12 pharmacist are licensed medical professionals, we as a  
13 prosecutor could not prosecute them for a crime.

14 THE COURT: But if they -- if, in all of those  
15 circumstances, they were a licensed medical provider, they  
16 got the drug from a licensed pharmacy that was manufactured  
17 by the plaintiff, if they performed an abortion using that  
18 drug, and that abortion was outside the restrictions that  
19 the State of West Virginia imposed in both of these Acts,  
20 but, in particular, the more recent more restrictive Act,  
21 they would be subject -- that provider would be subject to  
22 prosecution for a crime.

23 MS. SCRAGG KARR: No, because they are exempt.  
24 Under the statute, it says, any person other than a licensed  
25 medical professional, as defined in 16-2R-2 -- which talks

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1 about how they have to be licensed in West Virginia -- who  
2 would then do a -- knowingly and willfully perform, induce,  
3 or attempt to perform an abortion.

4 So it's any person other than that licensed medical  
5 professional.

6 So I think in this case what the plaintiff is probably  
7 looking at is the medical professional would be at -- have  
8 the potential to have their license revoked if they  
9 prescribed this pill in violation of the code section.

10 THE COURT: But you think that's the only penalty  
11 that a licensed provider would be subject to if they  
12 performed an abortion at 18 weeks, using mifepristone? And  
13 I know that's outside of the time they said.

14 MS. SCRAGG KARR: That's correct. That's how I  
15 read the statute. So by having that licensed medical -- the  
16 medical license would prevent them from being prosecuted.

17 THE COURT: Okay. Thank you.

18 (An off-the-record discussion was held between the  
19 Court and law clerk.)

20 THE COURT: All right. And my clerk is reminding  
21 me that the penalty section provides that on the first  
22 instance of a violation, they can be sanctioned on their  
23 license, but if they did it again, a second one, they'd be  
24 subject to criminal penalties.

25 MS. SCRAGG KARR: Well, actually what it says at

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1 subsection (b) of that 61-2-8, and that says, a person who  
2 was formerly a licensed medical professional.

3 Then -- and so, still again, they would be a person who  
4 no longer was a licensed medical professional. So  
5 regardless of how many abortions the medical professional  
6 would have authorized or conducted, it wouldn't matter under  
7 that code section.

8 I think what maybe your law clerk is thinking is once  
9 they would perform an illegal abortion or have one  
10 performed, then they would lose their license through a  
11 procedure of the code, and then once they lost that, if they  
12 did another one, they could be prosecuted. That would be  
13 true. They would no longer be a medical professional.

14 THE COURT: All right. Thank you for clarifying  
15 that.

16 All right, anything else?

17 MS. SCRAGG KARR: No, Your Honor.

18 THE COURT: I'll give you've a few minutes for  
19 rebuttal.

20 MR. FREDERICK: Let me start with the prosecutor,  
21 because the prosecutor has not disavowed an intent to  
22 enforce the statute. And that failure to disavow is  
23 particularly critical for pharmacies, which are not exempt  
24 from the statute, or nurse practitioners, who are not exempt  
25 from the statute, and who, under the FDA guidance, are able

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1 to provide mifepristone to pregnant women.

2 And so however much today's argument might focus on  
3 doctors, it doesn't address an issue that goes to standing  
4 under the third-party doctrine, under pre-enforcement  
5 challenges, which they don't acknowledge.

6 We are allowed to bring a pre-enforcement challenge to  
7 the law under the *Susan B. Anthony* case. And by the plain  
8 terms of the state statute, it encompasses people that are  
9 protected by the FDA 2023 REMS.

10 The Ban includes criminal penalties for pharmacies at  
11 61-2-8, which we cited in our opposition to the prosecutor's  
12 motion at 11, pharmacists are not licensed medical  
13 professionals within the meaning of the statute. And  
14 because they face criminal penalties, I think that the  
15 prosecutor really, respectfully, has to stay in the case.  
16 There is not a way to avoid that, given past statements  
17 about intending to enforce the statute as it is written.

18 With respect to the attorney general, I'm perplexed by  
19 the argument made today, frankly, because what the attorney  
20 general seems to be saying is that we can -- we can go after  
21 all the people who create the market for mifepristone, the  
22 doctors, the pharmacists, the nurse practitioners and  
23 everybody else, and it doesn't matter that it constricts  
24 your economic losses. Somehow the maker of the drug and the  
25 distributor in the state of the drug doesn't have standing

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1 to say the state law is unconstitutional.

2 That doesn't make any sense.

3 And the fact that the *Ezell* case is pretty much on  
4 point -- and let me give you the citation. It is 62 F.3d at  
5 692, Your Honor -- says that the firing range facility  
6 operator intended to create a facility in Chicago. It  
7 didn't have one at the time. It was doing them throughout  
8 the nation.

9 So it simply can't be the case that someone seeking to  
10 do business in a location but for a constitutional  
11 prohibition lacks standing in order to challenge the  
12 unconstitutionality of the statute.

13 I'm happy to address any of the other issues, but I  
14 don't think there is a serious argument here today that we  
15 lack standing to challenge the West Virginia statute.

16 And I look forward to the Court's decision and the  
17 opportunity to litigate the merits further.

18 THE COURT: All right. Thank you.

19 So you can take your seat.

20 Here's my plan. I would decide this within the next  
21 few days. I'll get started today. And within the next  
22 several days, I'll make a decision. And if I think I can  
23 get an opinion written on it within a few more days, like  
24 the next week or 10 days, you'll just hear -- you'll get all  
25 that at once, one way or the other.

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1           If I think it's going to take me much longer than that,  
2 for some reason, then I might short-order just saying that  
3 we have found or not found standing and an opinion will  
4 follow.

5           A lot of it just depends on what else comes into the  
6 Court that I've got to address between now and then, but my  
7 plan would be to decide this pretty quickly.

8           If I decide there is standing, then what I would hope  
9 to do is -- if I cannot get too distracted by other cases --  
10 to spend enough time on the other issues that are raised in  
11 the motion to dismiss, so that I can have a meaningful  
12 argument session with you again. And I'm really hoping I  
13 can do that within the next month.

14          My plan would be to try to -- if I can get up to speed  
15 on it -- bring you in some time in the middle, latter part  
16 of May and let you do oral argument on the remaining issues.  
17 And then be prepared to submit it and try to get it decided  
18 as quickly as I can at that point. Okay?

19          As much as I can do. All right.

20          Thank you all for your appearance today and your  
21 argument. I appreciate it.

22          (Proceedings concluded at 2:55 p.m.)

23

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25

1 CERTIFICATE OF OFFICIAL REPORTER  
2

I, Catherine Schutte-Stant, Federal Official Realtime  
3 Court Reporter, in and for the United States District Court  
4 for the Southern District of West Virginia, do hereby  
5 certify that, pursuant to Section 753, Title 28, United  
6 States Code, the foregoing is a true and correct transcript  
7 of the stenographically reported proceedings held in the  
8 above-entitled matter and that the transcript page format is  
9 in conformance with the regulations of the Judicial  
10 Conference of the United States.

11

12 s/Catherine Schutte-Stant, RDR, CRR

13

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May 17, 2023

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Catherine Schutte-Stant, RDR, CRR  
15 Federal Official Court Reporter

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